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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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RATNER PRESTIA P.O. BOX 980 VALLEY FORGE, PA 19482			PROCTOR, JASON SCOTT	
			ART UNIT	PAPER NUMBER
			2123	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/679,725	Applicant(s) WHIRLEY ET AL.	
	Examiner Jason Proctor	Art Unit 2123	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 April 2006.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12, 14-27, 29-39, 41, 42, 54-65, 67-81, 83-94, 96-98 and 112-123 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12, 14-27, 29-39, 41, 42, 54-65, 67-81, 83-94, 96-98 and 112-123 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 January 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-42, 54-98, and 112-123 were rejected in Office Action of 7 February 2006. Applicants' response dated 24 April 2006 has amended claims 1, 8-12, 15, 16, 23-27, 29-31, 36-39, 41, 42, 60-65, 68-70, 77-81, 85, 86, 91-94, 98, and 120; and cancelled claims 13, 28, 40, 66, 82, and 95. Claims 1-12, 14-27, 29-39, 41, 42, 54-65, 67-81, 83-94, 96-98, and 112-123 are pending in this application.

Claims 1-12, 14-27, 29-39, 41, 42, 54-65, 67-81, 83-94, 96-98, and 112-123 are rejected.

Claim Rejections - 35 USC § 112

The previous rejections under 35 U.S.C. § 112, second paragraph, of claims 8-13, 15, 23-28, 30, 36-40, 42, 61-66, 69, 77-82, 85, 91-95, and 98 for the use of trademark terms has been withdrawn in response to the amendments and/or cancellation of those claims.

The previous rejections under 35 U.S.C. § 112, second paragraph, of claims 12-13, 27-28, 39-40, 65-66, 81-82, and 94-95 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention have been withdrawn in response to Applicants' remarks.

Claim Objections

The previous objections to claim 120 have been withdrawn in response to Applicants' amendments and remarks.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1-3, 9, 16-18, 24, 31, 32, 36, 54, 56, 62, 70, 72, 78, 86, 91, 113, 115, 117, 118, and 119 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent No. 5,594,651 to St. Ville.

Regarding claims 1, 3, 16, 18, 31, 54, 56, 70, 72, and 86, St. Ville discloses a system for analyzing medical devices (abstract; column 16, lines 37-58) comprising:

A geometry generator that receives three-dimensional volumetric data of at least one anatomical feature and generates a geometric model of said anatomical feature [*"First, a finite element model of the normal bone geometry ... is created."* (column 16, lines 44-45); *"For example, the initial geometric model in the case of a prosthetic hip can be generated by X-raying a cadaveric hip using, for example, a Siemens Somatom DR3 or a GE 9800 CT scanner. This image data may be converted to a format usable by the CAD software package or may be converted to a format usable by finite element software package (for example, a PDA-PATRAN (available from PDA Engineering) format) to be described below."* (column 9, lines 31-38)];

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A mesh generator that receives said geometric model of said anatomical features and a geometric model of a medical device, and generates a finite element model or mesh based on both of said geometric model of said anatomical features and said geometric model of said medical device [*“A finite element model is again created, but now includes another layer, namely, the artificial hip embedded in the cancellous bone area.”* (column 17, lines 4-6); FIGS. 4A, 4B]; and

A stress/strain/deformation analyzer that receives said finite element model or mesh materials properties of said anatomical features and said medical device, load data on said anatomical features, and/or said medical device, and simulates an interaction between said anatomical features and said medical device to determine the predicted stresses, strains, and deformations of said medical device [*“a finite element analysis may be performed using the fine mesh model of FIG. 6 which includes 5207 nodes and 5040 isoparametric solid elements.”* (column 17, lines 4-9); *“In the case of the prosthetic hip, the defined potentials are the desired displacements (which correlate mathematically to the stresses) in the prosthetic hip when the prosthetic hip is subjected to the mechanical forces shown in FIGS. 4A and 4B during walking and rising from a chair.”* (column 8, lines 26-30)].

Claims 16, 31, 54, 70, and 86 recite systems and the methods performed by those systems which are substantially identical to the system of claim 1 or present limitations that have been addressed above. These claims are rejected rationale similar to that given above for claim 1.

Claims 18, 56, and 72 reiterate the limitations of claim 3 which have been addressed above. These claims are rejected rationale similar to that given above for claim 3.

Regarding claims 2, 17, and 32 St. Ville discloses that the geometric model of said anatomical features is an idealized geometric model [“*First, a finite element model of the normal bone geometry ... is created. The stiffness properties of each layer are then defined... These stiffness properties and loads are known quantities which have been published in numerous journals...*” (column 16, lines 44-58)].

Claims 17 and 32 reiterate the limitations of claim 2 which have been addressed above. These claims are rejected rationale similar to that given above for claim 3.

Regarding claims 9, 24, 36, 62, 78, and 91, St. Ville discloses that the mesh generator includes three-dimensional finite modeling software [“*Other suitable software packages for generating the finite element model include MSC/NASTRAN [...], ABAQUS [...], and ANSYS [...].*” (column 9, lines 54-59)].

Regarding claims 113, 115, 117, 118, and 119, St. Ville discloses that the simulated stresses, strains, and deformations imposed on said medical device comprise dynamic or quasi-static stresses, strains, and deformations [“*mechanical forces shown in FIGS. 4A and 4B during walking and rising from a chair.*” (column 8, lines 25-30)].

Claims 115, 117, 118, and 119 reiterate the limitations of claim 113 which have been addressed above. These claims are rejected rationale similar to that given above for claim 113.

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In response to the rejection of independent claims 1, 16, 31, 54, 70, and 86 above,

Applicants argue primarily that:

Nowhere does St. Ville teach or suggest generating a finite element model or mesh based on both a geometric model of an anatomical feature and a geometric model of a medical device. Instead, St. Ville only teaches generating a finite element model of the object to be manufactured. St. Ville discusses two exemplary objects to be manufactured, namely, a gold club shaft and a composite replacement hip. The disclosure relating to the composite replacement hip is cited as teaching the generation of a finite element model or mesh based on both a geometric model of an anatomical feature and a geometric model of a medical device. [...] However, such discussion is limited to the generation [of] a geometric model of the "object to be manufactured", not of an anatomical feature to be analyzed in conjunction with the medical device.

The Examiner respectfully traverses this argument as follows.

The claims do not require "generation of a geometric model of an anatomical feature in conjunction with a model [the object or device]." as suggested by Applicants' arguments. The claims do require "a finite element model or mesh based on both of said geometric model of said anatomical feature(s) and said geometric model of said medical device" (claim 1). As cited in the body of the rejection, St. Ville discloses the generation of a model of at least one anatomical feature (column 9, lines 31-38) which is in turn used to generate a finite element model or mesh of a medical device based on the geometric model (column 17, lines 4-6). Therefore it appears clear to the Examiner that St. Ville's "object to be manufactured" meets the claim language by disclosing "a finite element model or mesh based on both a geometric model of an anatomical feature and a geometric model of a medical device."

At the very least, it seems reasonable to conclude that a prosthetic hip is a medical device that is at least based on an anatomical feature, i.e. an anatomically correct hip which is to be replaced by the prosthesis.

Applicants further argue that:

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Figure 6 is also cited as depicting “an anatomical feature (bone structure) and medical device (prosthetic hip joint).” Applicants respectfully submit that Figure 6 does not depict an anatomical feature, but instead only depicts the object to be manufactured, namely, the composite replacement hip. [...] St. Ville fails to teach or suggest a mesh generator that generates a finite element model or mesh based on both of said geometric model of said anatomical feature(s) and said geometric model of said medical device.

The Examiner has reviewed the reference and concurs with Applicants’ remarks on this point.

The Examiner thanks Applicants for correcting this oversight. However, the Examiner does not find this point persuasive in overcoming the grounds of rejection for the reasons set forth above.

Applicants further argue that:

Furthermore, St. Ville only teaches applying static force values to the object to be manufactured and does not teach or suggest simulating an interaction between said anatomical feature(s) and said medical device to determine the predicted stresses, strains, and deformations of said medical device. [*cit. omitted*] The forces that are input [in St. Ville] are static figures, independent of the configuration of any specific anatomical feature(s) associated with the composite replacement hip. There is no teaching or suggestion of a stress/strain/deformation analyzer that simulates an interaction between said anatomical feature(s) and said medical device to determine the predicted stress, strains, and deformations of said medical device.

The Examiner respectfully traverses this argument as follows.

The claims do not require a “configuration of any specific anatomical feature,” nor do the claims exclude “static forces.” The claims do require “simulat[ing] an interaction between said anatomical feature(s) and said medical device to determine the predicted stresses, strains, and deformations of said medical device” which has shown in the St. Ville reference in the rejection and in Applicants’ remarks.

The St. Ville reference discloses simulating the stresses, strains, and deformations of a medical device (a prosthetic hip) during a loading situation [“one-leg stance”, during walking, rising from a chair, etc. (column 8, lines 3-15)]. St. Ville explicitly discloses that these are “*the mechanical forces which will be applied to the prosthetic hip after implant in the human body.*” (column 8, lines 3-5)

In general, Applicants appear to be in favor of an interpretation of the invention that is narrower than the claim language. The Examiner notes that St. Ville may not explicitly disclose, for example, a *single* finite element model or mesh depicting *both an anatomical feature and a medical device*, however there is no requirement in the claim language for that feature. The broadly recited language “a finite element model or mesh **based** on both [an anatomical feature] and [a medical device]” is clearly open to an interpretation at least as broad as that presented in the rejection.

The Examiner has fully considered Applicants’ arguments but has found them unpersuasive.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. § 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

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2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. § 103(c) and potential 35 U.S.C. § 102(e), (f) or (g) prior art under 35 U.S.C. § 103(a).

2. Claims 4, 19, 57, and 73 are rejected under 35 U.S.C. § 103(a) as being unpatentable over St. Ville as applied to claims 1, 16, 54, and 70 above, and further in view of US Patent No. 5,880,976 to DiGioia III et al. (DiGioia).

St. Ville does not expressly teach acquiring three-dimensional volumetric data via MRI.

DiGioia teaches several techniques of acquiring structural data of a skeletal structure, including MRI [*“Commonly used tomographic techniques include computed tomography (CT), magnetic resonance imaging (MRI), positron emission tomographic (PET), or ultrasound scanning of the joint and surround structure. The tomographic data from the scanned structure generated by the skeletal data source 13 is provided to the geometric planner 12 for use in producing a model of the skeletal structure.”* (column 7, lines 8-14)].

St. Ville and DiGioia are analogous art because both are directed to modeling prosthetic implants.

Therefore, it would have been obvious to a person of ordinary skill in the art at the time of Applicants' invention to combine the imaging techniques taught by DiGioia in the modeling system of St. Ville because DiGioia expressly teaches how to provide for the proper placement and implantation of the joint components to provide an improved range of motion and usage of the joint following joint reconstruction, replacement, and revision surgery (DiGioia, column 4, lines 50-60).

Claims 19, 57, and 73 reiterate the limitations of claim 4 which have been addressed above. These claims are rejected for rationale similar to that given above for claim 4.

3. Claims 5-7, 20-22, 33-35, 58-60, 74-76, and 88-90 are rejected under 35 U.S.C. § 103(a) as being unpatentable over St. Ville as applied to claims 1, 16, 31, 54, 70, and 86 above, and further in view of "A Finite Element Treatment of the In-Vivo Loading Conditions of NiTi Vascular Stent and Graft Structures" by F. Whitcher (Whitcher, provided by Applicants via PTO-1449 submitted on 3 February 2005).

St. Ville does not expressly teach that the medical device as an endovascular prosthesis, a stent graft, or a cardiovascular stent.

Whitcher teaches finite element simulation analysis of "vascular support structures (stents and grafts) to provide designers with estimates of their in-vivo structural behavior and fatigue properties" (abstract).

St. Ville and Whitcher are analogous art because both are directed to finite element analysis of medical devices.

Therefore it would have been obvious to a person of ordinary skill in the art at the time of Applicants' invention to combine the analysis of cardiovascular stents and grafts as taught by Whitcher with the modeling system of St. Ville because Whitcher expressly teaches that "there is a high priority to deliver high performance vascular stents to the health care practitioner" (page 607, "Introduction") and Whitcher's method provides "simulation analysis of vascular support structures (stents and grafts), to provide designers with estimates of their in-vivo structural behavior and failure properties" (abstract), thereby providing a solution that makes it easier to design and provide successful vascular stents to the health care practitioner.

Claims 20-22, 33-35, 58-60, 74-76, and 88-90 reiterate the limitations of claims 5-7 which have been addressed above. These claims are rejected for rationale similar to that given above for claims 5-7.

4. Claims 8, 23, 61, and 77 are rejected under 35 U.S.C. § 103(a) as being unpatentable over St. Ville as applied to claims 1, 16, 54, and 70 above, and further in view of "Automated Mesh Generation of an Arterial Bifurcation Based upon *In Vivo* MR Images" by Seung Lee et al. (Lee).

St. Ville does not expressly disclose that the geometry generator is a software application which generates surface points from the three-dimensional volumetric data, which are then converted into stereolithography, slice files, IGES files or a combination thereof.

Lee teaches methods for creating a CFD mesh of a blood vessel based on in vivo measurements taken by magnetic resonance image (abstract). Lee teaches generating 3D-lumen geometry using Mimics (page 1, right column) from MR imaging data (page 1, left and right columns).

St. Ville and Lee are analogous art because both are directed to imaging and modeling of anatomy.

Therefore it would have been obvious to a person of ordinary skill in the art at the time of Applicants' invention to combine the use of MIMICS to interpret MRI data and generate geometry as taught by Lee in the modeling system of St. Ville because Lee expressly teaches that "the goal of this study was to develop an automated mesh generation technique based on measurements of *in vivo* lumen geometry using MR," (page 1, left column) and therefore provides an automation solution to that step of the modeling process.

Claims 23, 61, and 77 reiterate the limitations of claim 8 which have been addressed above. These claims are rejected for rationale similar to that given above for claim 8.

5. Claims 10-12, 25-27, 37-39, 63-65, 67, 79-81, 83, 92-94, 96, 112, 114, and 116 are rejected under 35 U.S.C. § 103(a) as being unpatentable over St. Ville as applied to claims 1, 16, 31, 54, 70, and 86 above, and further in view of "Computational Mechanics Moves Ahead" by Peter J. Raboin (Raboin).

Regarding claims 10-11, St. Ville does not expressly disclose that the stress/strain/deformation analyzer is a non-linear finite element modeling software application or that the three-dimensional finite modeling software tessellates a geometric model into hexahedron brick elements and quadrilateral shell elements to create the mesh.

Raboin teaches several computational mechanics codes for finite element analysis (page 2 of 13, "Structural Problems, Computer Solutions") including DYNA3D (pages 3-6 of 13, "Two Classes of Codes") and NIKE3D (pages 6-8 of 13, "NIKE3D for Biomechanics") for "studying

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dynamic, finite deformations, [which] can model the behavior of joint tissues and bones subjected to different loads and joint movement with and without prosthetic implants (pages 6-7 of 13).

St. Ville and Raboin are analogous art because both are directed to modeling of prosthetic joints.

Therefore it would have been obvious to a person of ordinary skill in the art at the time of Applicants' invention to use one of the computational mechanics codes taught by Raboin in the modeling system of St. Ville because Raboin expressly teaches that the finite element methods have "powerful versatility" that can model "numerous nonlinear material behaviors" (page 2 of 13) and therefore allow greater flexibility in performing a wider variety of simulations.

Claims 25-26, 37-38, 63-64, 79-80, and 92-93 reiterate the limitations of claims 10-11 which have been addressed above. These claims are rejected for rationale similar to that given above for claims 10-11.

Claims 12, 27, 39, 65, 81, and 94 have been interpreted as set forth above and are therefore rejected for rationale similar to that given above for claims 10-11.

Regarding claim 112, St. Ville does not expressly disclose that the stress/strain/deformation analyzer uses a non-linear finite element analysis tool.

Raboin teaches that NIKE3D is a "Nonlinear, three-dimensional, finite-element modeling" tool (page 6 of 13, "NIKE3D for Biomechanics"). Therefore, claim 112 is rejected rationale similar to that given above for claim 11.

Claims 67, 83, 96, 114, and 116 reiterate the limitations of claim 112 which have been addressed above. These claims are rejected for rationale similar to that given above for claim 112.

6. Claims 14-15, 29-30, 41-42, 68-69, 84-85, and 97-98 are rejected under 35 U.S.C. § 103(a) as being unpatentable over St. Ville as applied to claims 1, 16, 31, 54, 70, and 86 above, and further in view of “GRIZ Finite Element Analysis Results Visualization for Unstructured Grids User Manual” by Douglas E. Speck and Donald J. Dovey (Dovey).

St. Ville does not expressly disclose the use of interactive software as a visualization tool that displays one or more of said stresses, strains, and deformations of said medical device via visual representation.

Dovey teaches that GRIZ is “a general-purpose post-processing application supporting interactive visualization of finite element analysis results on unstructured grids. GRIZ calculates and displays derived variables for a variety of analysis codes. Currently, GRIZ works with the family of Methods Development Group (MDG) analysis codes, including DYNA3D, NIKE3D, and TOPAZ3D.” (page 1, “Introduction”). Dovey teaches that GRIZ displays the results of various parameters (page 21, “Results Command”), including various stress results variables (*ex.* “sx”, page 21); strain variables (*ex.* “ex”, page 22); and deformation (*ex.* “dispx”, page 24).

St. Ville and Dovey are analogous art because both are directed toward finite element analysis.

Therefore, it would have been obvious to a person of ordinary skill in the art at the time of Applicants’ invention to use GRIZ as taught by Dovey to visualize the results of the modeling

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system of St. Ville because Dovey expressly teaches that “GRIZ provides flexible control of mesh materials on an individual basis, allowing the user to concentrate analysis and visual focus on important subsets of the mesh. GRIZ incorporates the ability to animate all representations over time,” thereby enhancing the analysis capabilities present in the system taught by St. Ville to increase productivity.

Claims 29-30, 41-42, 68-69, 84-85, and 97-98 reiterate the limitations of claims 14-15 which have been addressed above. These claims are rejected for rationale similar to that given above for claim 14-15.

7. Claims 55, 71, 87, and 120-123 are rejected under 35 U.S.C. § 103(a) as being unpatentable over St. Ville as applied to claims 54, 70, and 86 above, and further in view of “Failure of All-ceramic Fixed Partial Dentures *in vitro* and *in vivo*: Analysis and Modeling” by J.R. Kelly, J.A. Tesk, and J.A. Sorensen (Sorensen).

Regarding claims 55, 71, and 87, St. Ville does not expressly disclose performing a simulation to the point of failure of the medical device.

Sorensen teaches performing a finite element analysis (FEA) of fixed partial denture medical devices (abstract) to the point of failure of the device [“*Weibull failure probability (P_f) calculations, incorporating FEA stress profiles... Observations from failed clinical restorations provided critical guidance in validating a laboratory test and focusing a mathematical failure model.*” (abstract); “*Fig. 3 is the finite element solution obtained when the abutment was rigidly fixed...*” (page 1255, right column – page 1256, left column, “Results”); “*Both the in vitro test*

examined and the mathematical model seem to capture a number of primary features of clinical failure, and as such are at least partially validated.” (page 1257, right column, “Discussion”)].

St. Ville and Sorensen are analogous art because both are directed to finite element analysis of medical devices.

Therefore it would have been obvious to a person of ordinary skill in the art at the time of Applicant’s invention to combine the failure mode tests taught by Sorensen in the modeling system of St. Ville because Sorensen expressly teaches that “[f]ailed structures provide valuable information for improving the design of components and in validating laboratory tests and structural models” (page 1253, left column, “Introduction”) and thereby improving the effectiveness and reliability of the final designs.

Regarding claims 120-123, St. Ville does not expressly disclose performing a failure mode simulation.

Sorensen teaches a geometric model of an *in vitro* failure mode test [*“Figure 4. Finite element solution when the abutment tooth is allowed to rotate... This result corresponds more closely to the fractographic findings [failure mode] than does the solution in Fig. 3”* (Fig. 4, caption)].

Sorensen teaches a step of simulating stresses, strains, and deformations imposed on said candidate medical device design in said *in vitro* failure mode test [*“Finite element analysis (FEA) of the laboratory FPDs found that maximum principal tensile stresses would occur at locations consistent with the fractographic observations...”* (abstract)].

Sorensen teaches comparing simulation data generated by said step of simulating and additional simulation data generated by said step of simulating an *in vitro* failure mode test [*“Both the in vitro test examined and the mathematical model seem to capture a number of primary features of clinical failure, and as such are at least partially validated.”* (page 1257, right column, “Discussion”); *“Fig. 5 is a plot of the probability of failure vs. failure load for data from the 20 laboratory FPDs along with calculated failure probabilities based upon the finite element results with abutment rotation allowed. Probabilities for the in vitro data were simply evaluated...”* (page 1256, left column, “Results”)].

Sorensen teaches that the *in vitro* failure mode test parameters, while not part of the disclosed model, are known in the art and the absence of this influence is a criticism of the disclosed model [*“Possible effects of damage accumulation due to cyclic loading (Suresh, 1991) are also not part of the model. These same criticisms hold for the laboratory test as well.”* (page 1257, right column, “Discussion”)].

St. Ville and Sorensen are analogous art because both are directed to finite element analysis of medical devices.

Therefore it would have been obvious to a person of ordinary skill in the art at the time of Applicant's invention to combine the failure mode tests taught by Sorensen in the modeling system of St. Ville because Sorensen expressly teaches that “[f]ailed structures provide valuable information for improving the design of components and in validating laboratory tests and structural models” (page 1253, left column, “Introduction”) and thereby improving the effectiveness and reliability of the final designs.

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In response to the rejections under 35 U.S.C. § 103, Applicants have submitted arguments that the independent claims are patentable. Those arguments have been addressed above and have been found unpersuasive.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jason Proctor whose telephone number is (571) 272-3713. The examiner can normally be reached on 8:30 am-4:30 pm M-F.


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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Paul Rodriguez can be reached at (571) 272-3753. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application should be directed to the TC 2100 Group receptionist: 571-272-2100. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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